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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,793	11/18/2003	Debbie Yaver	10351.200-US	8797

25907 7590 10/21/2005

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EXAMINER	
LAMBERTSON, DAVID A	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,793	YAVER ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,25-28,30,31,53,62,77-80,82,83 and 87-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,10,25-28,30,31,53,62,77-80,82,83 and 87-90.

DETAILED ACTION

Receipt is acknowledged of a preliminary amendment, filed November 18, 2003. Amendments were made to the claims. Specifically, claims 2-9, 11-24, 29, 32-52, 54-61, 63-76, 81 and 84-86 were cancelled.

Claims 1, 10, 25-28, 30, 31, 53, 62, 77-80, 82, 83 and 87-90 are pending and subject to restriction in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1, 10, 25, 27, 28, 30, 31 and 90, drawn to a method of producing a biological substance comprising operably linking a first nucleic acid of interest encoding the biological substance to a second nucleic acid of interest comprising a promoter variant or hybrid comprising SEQ ID NO: 2 or a subsequence thereof, classified in class 435, subclass 41.
2. Claims 1, 10, 25, 27, 28, 30, 31 and 90, drawn to a method of producing a biological substance comprising operably linking a first nucleic acid of interest encoding the biological substance to a second nucleic acid of interest comprising a promoter variant or hybrid comprising SEQ ID NO: 3 or a subsequence thereof, classified in class 435, subclass 41.
3. Claims 1, 10, 25, 27, 28, 30, 31 and 90, drawn to a method of producing a biological substance comprising operably linking a first nucleic acid of interest encoding the biological substance to a second nucleic acid of interest comprising

a promoter variant or hybrid comprising SEQ ID NO: 4 or a subsequence thereof, classified in class 435, subclass 41.

4. Claims 1, 10, 25, 27, 28, 30, 31 and 90, drawn to a method of producing a biological substance comprising operably linking a first nucleic acid of interest encoding the biological substance to a second nucleic acid of interest comprising a promoter variant or hybrid comprising SEQ ID NO: 5 or a subsequence thereof, classified in class 435, subclass 41.

5. Claims 1, 10, 26, 27, 28, 30, 31 and 90, drawn to a method of producing a biological substance comprising operably linking a first nucleic acid of interest encoding the biological substance to a second nucleic acid of interest comprising a promoter variant or hybrid comprising SEQ ID NO: 6 or a subsequence thereof, classified in class 435, subclass 41.

6. Claims 1, 10, 26, 27, 28, 30, 31 and 90, drawn to a method of producing a biological substance comprising operably linking a first nucleic acid of interest encoding the biological substance to a second nucleic acid of interest comprising a promoter variant or hybrid comprising SEQ ID NO: 7 or a subsequence thereof, classified in class 435, subclass 41.

7. Claims 1, 10, 26, 27, 28, 30, 31 and 90, drawn to a method of producing a biological substance comprising operably linking a first nucleic acid of interest encoding the biological substance to a second nucleic acid of interest comprising a promoter variant or hybrid comprising SEQ ID NO: 8 or a subsequence thereof, classified in class 435, subclass 41.

8. Claims 1, 10, 26, 27, 28, 30, 31 and 90, drawn to a method of producing a biological substance comprising operably linking a first nucleic acid of interest encoding the biological substance to a second nucleic acid of interest comprising a promoter variant or hybrid comprising SEQ ID NO: 9 or a subsequence thereof, classified in class 435, subclass 41.

9. Claims 1, 10, 26, 27, 28, 30, 31 and 90, drawn to a method of producing a biological substance comprising operably linking a first nucleic acid of interest encoding the biological substance to a second nucleic acid of interest comprising a promoter variant or hybrid comprising SEQ ID NO: 10 or a subsequence thereof, classified in class 435, subclass 41.

10. Claims 1, 10, 26, 27, 28, 30, 31 and 90, drawn to a method of producing a biological substance comprising operably linking a first nucleic acid of interest encoding the biological substance to a second nucleic acid of interest comprising a promoter variant or hybrid comprising SEQ ID NO: 11 or a subsequence thereof, classified in class 435, subclass 41.

11. Claims 1, 10, 26, 27, 28, 30, 31 and 90, drawn to a method of producing a biological substance comprising operably linking a first nucleic acid of interest encoding the biological substance to a second nucleic acid of interest comprising a promoter variant or hybrid comprising SEQ ID NO: 12 or a subsequence thereof, classified in class 435, subclass 41.

12. Claims 53, 62, 77, 79, 80, 82, 83 and 87-89, drawn to a promoter element or hybrid comprising SEQ ID NO: 2 or subsequences thereof. Vectors comprising

said promoter and host cells comprising said vector, classified in class 536, subclass 24.1.

13. Claims 53, 62, 77, 79, 80, 82, 83 and 87-89, drawn to a promoter element or hybrid comprising SEQ ID NO: 3 or subsequences thereof. Vectors comprising said promoter and host cells comprising said vector, classified in class 536, subclass 24.1.

14. Claims 53, 62, 77, 79, 80, 82, 83 and 87-89, drawn to a promoter element or hybrid comprising SEQ ID NO: 4 or subsequences thereof. Vectors comprising said promoter and host cells comprising said vector, classified in class 536, subclass 24.1.

15. Claims 53, 62, 77, 79, 80, 82, 83 and 87-89, drawn to a promoter element or hybrid comprising SEQ ID NO: 5 or subsequences thereof. Vectors comprising said promoter and host cells comprising said vector, classified in class 536, subclass 24.1.

16. Claims 53, 62, 78-80, 82, 83 and 87-89, drawn to a promoter element or hybrid comprising SEQ ID NO: 6 or subsequences thereof. Vectors comprising said promoter and host cells comprising said vector, classified in class 536, subclass 24.1.

17. Claims 53, 62, 78-80, 82, 83 and 87-89, drawn to a promoter element or hybrid comprising SEQ ID NO: 7 or subsequences thereof. Vectors comprising said promoter and host cells comprising said vector, classified in class 536, subclass 24.1.

18. Claims 53, 62, 78-80, 82, 83 and 87-89, drawn to a promoter element or hybrid comprising SEQ ID NO: 8 or subsequences thereof. Vectors comprising said promoter and host cells comprising said vector, classified in class 536, subclass 24.1.

19. Claims 53, 62, 78-80, 82, 83 and 87-89, drawn to a promoter element or hybrid comprising SEQ ID NO: 9 or subsequences thereof. Vectors comprising said promoter and host cells comprising said vector, classified in class 536, subclass 24.1.

20. Claims 53, 62, 78-80, 82, 83 and 87-89, drawn to a promoter element or hybrid comprising SEQ ID NO: 10 or subsequences thereof. Vectors comprising said promoter and host cells comprising said vector, classified in class 536, subclass 24.1.

21. Claims 53, 62, 78-80, 82, 83 and 87-89, drawn to a promoter element or hybrid comprising SEQ ID NO: 11 or subsequences thereof. Vectors comprising said promoter and host cells comprising said vector, classified in class 536, subclass 24.1.

22. Claims 53, 62, 78-80, 82, 83 and 87-89, drawn to a promoter element or hybrid comprising SEQ ID NO: 12 or subsequences thereof. Vectors comprising said promoter and host cells comprising said vector, classified in class 536, subclass 24.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions Groups 1-11 are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Specifically, each method makes use of a different specific nucleic acid sequence that comprises the promoter variant or hybrid thereof. Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such sequences to be claimed in a single application. Under this policy, a single independent and distinct sequence will be examined in a single application. The sequences are considered to be unrelated since each sequence claimed is structurally and functionally independent and distinct. Furthermore, a search of more than one (1) of the sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. Because each method makes use of a patentably distinct sequence, the method steps therein are considered to be patentably distinct as well. As such, each method (wherein a different sequence is used) in considered to have different modes of operation, involving each particular sequence. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

Inventions Groups 12-21 are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Specifically, each product comprises a different specific nucleic acid sequence that comprises the promoter variant or hybrid thereof. Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such sequences to be claimed in a single application. Under this policy, a single independent and distinct sequence will be examined in a single application. The sequences are considered to be unrelated since each sequence claimed is structurally and functionally independent and distinct. Furthermore, a search of more than one (1) of the sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. Because each product has a patentably distinct sequence, the method steps therein are considered to be patentably distinct as well. As such, each product (comprising a different sequence) is considered to have different modes of operation, each involving the use of a particular sequence. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

The following groupings of inventions are related as product and process of use: Groups 1 and 12; Groups 2 and 13; Groups 3 and 14; Groups 4 and 15; Groups 5 and 16; Groups 6 and 17; Groups 7 and 18; Groups 8 and 19; Groups 9 and 20; Groups 10 and 21; and Groups 11 and 22. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of making a biological substance can be produced using any number of promoter elements, such as any one of SEQ ID NOS: 2-12, or a generic well-known promoter that is operational in an organism of interest. Furthermore, the products as claimed can each be used for a materially different purpose, such as a probe to identify orthologous sequences in additional organisms. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

The following groupings of inventions are unrelated: Groups 1 and 13-22; Groups 2 and 12, 14-22; Groups 3 and 12, 13, 15-22; Groups 4 and 12-14, 16-22; Groups 5 and 12-15, 17-22; Groups 6 and 12-16, 18-22; Groups 7 and 12-17, 19-22; Groups 8 and 12-18, 20-22; Groups 9 and 12-19, 21-22; Groups 10 and 12-20, 22; Groups 11 and 12-21. Inventions are unrelated if it

can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Specifically, each method of producing a biological substance (Groups 1-11) makes use of a patentably distinct promoter sequence, and thus cannot be practiced using the products as set forth above in each particular pairing. For instance, Group 1 requires that a promoter element comprising SEQ ID NO: 2 be used; however, neither of Groups 13-22 requires the use of such an element, thus the method (Group 1) has a mode of operation that is different from the products of Groups 13-22 because it uses a promoter element that has a different sequence from the elements in those Groups. The same example can be put forth for each of the methods of Groups 2-12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

Election of Species

Each of the claims are generic to a plurality of disclosed patentably distinct species comprising different hybrid promoter sequences, wherein the different hybrids include combinations of patentably distinct sequences. When electing one of Groups 1-22 as set forth above, Applicant is required to additionally elect a species of hybrid promoter as it relates to the

sequences. For example, if Applicant elects Group 1 above, Applicant should indicate a hybrid promoter species such as a hybrid between SEQ ID NO: 2 and SEQ ID NO: 3 (or subsequences thereof), a hybrid between SEQ ID NO: 2 and SEQ ID NO: 4 (or subsequences thereof), and so on for each of the sequences as listed in the groups. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636

JAMES KETTER
PRIMARY EXAMINER